ECOFRAM, Aquatic Peer Review Meeting

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General

The ECOFRAM Aquatic Workgroup on Exposure and Effects did a very good job in preparing the document under consideration. It gives an extensive overview on what is currently possible and feasible to perform risk assessments in the aquatic environment at all levels of concern. The state-of-the-art is well described and documented. Therefore, the report is to be considered as a valuable contribution to risk assessment methodologies, as they have to be carried out in the registration of plant protection products in the agricultural field. The workgroup needs firm congratulations for the establishment of this thorough draft on this subject.

Of course, several improvements are possible in explaining some items and subjects in a little more detail, screen the document on duplications and consistencies, removal of typing errors, increase the quality of figures and tables, and to add additional text for the areas already indicated in the report. But these suggestions are of minor importance compared to the overall value of the report.

A suggestion might be to remove several pages of the document because they are already mentioned in other parts and because there is still an Executive Overview to be added. The “Overviews” are sometimes a little overdone.

Charge to Panel Members:

1 Is the draft report scientifically sound? If not, please explain and provide specific suggestions on how to improve the report to make it scientifically sound.

Yes, in my opinion the report in general is scientifically sound. Some improvements may be required in the area of consistency with respect to detailed versus more global treatment of subjects. The certainty and / or uncertainty should be of more or less equal or comparative in the description of e.g. processes. Example: role of photolysis in relation to information requirements, activation energy of radical formation.
It is not useful to describe a process very detailed when the description of other processes lacks this level of detail.
Nevertheless, some suggestions for improvement are indicated below. These suggestions are not affecting the general usefulness but should be considered as a contribution to the accurateness of the message.

2 Did the ECOFRAM Workgroup address the “Charge to the Terrestrial and Aquatic Workgroups” identified in the background document, “Evaluating Ecological Risk: Developing FIFRA Probabilistic Tools and Processes” (Attachment #3)? If not, please explain why not and provide specific suggestions on how the “Charge” could be addressed.

This question should in my opinion be answered with a clear YES. I do not have any reservations on this point.

3 What are the limitations for predicting risk using the approach described in the draft report? Please, provide specific suggestions.

The limitations for predicting risk using whichever approach will in my opinion always be the level of characterising reality using models or stochastic or probabilistic modelling. Every model is an abstraction of reality how close the reality may be approximated. Even validation of deterministic or probabilistic models will not change this. The crucial point is the degree of trust risk assessors and risk managers have in the models. The models developed and used in risk assessment should be considered as the most sophisticated method available, in which current knowledge on the specific subject is brought together.
It is difficult to distinguish the suggestions in relation to the questions. Therefore, I will mention my questions, remarks and suggestions in one listing below.

4 Taking into account your answers to the three questions above, what areas of the report need to be strengthened? If possible, please, provide specific recommendations for how to strengthen the report.

The main area in my view that could lead to an improvement of the document would be a reduction of duplications and repetitions of items, lists, and figures. Sometimes it is useful to repeat things to make the point you want to make clear. As indicated some listing are concerned with the same subject but are just slightly different, e.g. the listings of objectives in chapter 2: Tier 1 on page 2-6 and 2-17; Tier 2 on page 2-7 and 2-21. This is confusing for the reader and the user.

5 At what point in the risk assessment process is the certainty high enough to support the consideration of risk mitigation? What is the minimum level of technical information and scientific understanding that is necessary to evaluate whether risk mitigation would be necessary and/or effective?

It is always timely in my view to consider and propose risk mitigation measures. The company may do so on a voluntary basis or of course based on the outcome of the risk assessment process. If at Tier 1 after having applied the GENEEC calculation a decision would be appropriate to move to Tier 2, already in this stage the company may decide in order not to be involved in time and money consuming additional tests or calculations to propose measures that reduce the EECs to a safe level.

Chapter 2

1. Excellent overview of all the possible steps in the risk assessment process. It is clear that the risk assessment process only is directed at higher Tiers to the organisms and compartments of potential concern. Although it is indicated that the separation between Tiers is not strict and that some flexibility is required in applying triggers and reasoning, I have the impression that an unnecessary distinction is made when calculations or evaluations of the data that may be done are not carried out because they would belong to the next Tier. In my view this is not a very scientific approach.

2. Page 2-17 is to be compared to page 2-6, as there seem to be different objectives for Tier 1. This is quite confusing for the reader / user.

3. Page 2-17, lines 19 – 21: this is a duplication of the lines 15 – 17.

4. Page 2-19, line 24: It is understood that Tier 1 is intended to be conservative. On the other hand it is quite clear that the peak EEC will not last during the time of the prolonged toxicity study because the substance will start to degrade. As the calculation has to be carried out anyway both comparisons may be made: the ratio of the peak EEC and the toxicity value and the ratio of the TWA EEC and the toxicity value, which in both cases will be the NOEC-value.

5. Page 2-21: if compared to page 2-7 there are differences in the objectives formulated. For easy reading it is suggested to adjust the wording.

6. Page 2-21, line 14: why should making ‘more complete use of the results of Tier 1 toxicity tests’ be postponed to Tier 2. Calculations and data analysis should in my view be done at any moment possible. This gives a clear understanding of the test results and also of the quality of the input data.

7. Page 2-22, line 16: what is the rationale behind the ‘at least’ 35-year of weather data? Often at least in Europe such a long history may not be available. Is it in the US? It seems that even a longer period would be advisable?

8. Page 2-22, line 26: the one-year estimate should also be included.

9. Page 2-22, line 29: tile drainage is not a major route of concern in the US? At other places it was mentioned. In areas with high water tables it may be useful to have a scenario for this situation available.

10. Page 2-23, line 22: Again my suggestion would be to use all information at the moment the information is available and do not wait until a higher Tier to take the information into account. Probably, fewer substances would move to higher Tiers.

11. Page 2-29, line 22: Here reduction of the number of compounds moving to Tier 3 seems appropriate. The question is how to achieve this. It might be possible that performing the most complete data analysis possible at any moment will help here.

12. Page 2-33, bottom end: although at page 2-35 some remark is made on the problem of bioavailability I think a more thorough treatment of this item would be required here. At least some references could be added to papers reviewing bioavailability. The same would be valid for the problem of possible effects of bound residues.

13. Page 2-36, line 10: it seems from the decisions at Tier 3 and the further wording that Tier 2 is not discriminative enough. In the discussions this might be a topic to keep in mind.

14. Page 2-49, line 34: international harmonisation is an important item. During the last years I tried to contribute to international harmonisation to some extent and I am very much supporting this goal. However, the proposals and recommendations of ECOFRAM do not contribute very much to international harmonisation because a complete new way is propose: probabilistic modelling. The EU and the rest of Europe probabilistic modelling are not very familiar with the subject. This means that international harmonisation is further away than ever. Of course, this does not mean that I am not in favour of the approach taken. The only thing is that more work will be required to bring forward the ideas of this advanced method of risk assessment.

Chapter 3

1. Page 3-4, line 1- 7: several data requirements are quite specific for the US. For example, quantum yields, foliar dissipation and uptake from plants are considered in EU legislation on PPP in 91/414. Of course, it is always possible that a specific problem would require such data, but certainly not on a routine basis.

2. Page 3-4, line 28 – 32: some years ago there has been carried out an OECD pilot project aiming at the comparison of data for 7 active substances and the possibilities in sharing the workload on summarising and evaluating these data. One of the conclusions was that the US summaries and evaluations were not very helpful for other authorities in clearness of conclusions and results. After the Bilthoven workshop in September 1995, where these and other conclusions and recommendations were discussed, OECD and EU started a project on the harmonisation of data requirements formats for industry and the harmonisation of data summaries and evaluations for governmental authorities. It seems that the conclusions, recommendations and formats developed may still need some wider impact in the US and EPA.

3. Page 3-5, line 15 – 19: At RIVM in the Netherlands we have prepared a report (RIVM report number 679101022) that may be helpful in the establishment of good input data required for risk assessments. It is very important that the data used are of good quality (Garbage in, garbage out). The report provides for each environmental study type a list of key parameters that have to be taken into account when determining an environmental endpoint. Some information is so important that it can render the study inadequate, others are more a matter of expert judgement. I hope the document will show useful.

4. Page 3-7, line 16: in my experience not many identified correlations exist. In NL we only use the Walker equation in our risk assessments: the relation between half-life time and soil moisture. In addition we use the Arrhenius-equation on temperature dependence of half-life time. Although this relation is established only for abiotic chemical transformations we also apply the relation to other types of transformation.

5. Page 3-7, line 35: In addition, it seems worthwhile to mention here the developments in IUPAC. A paper is currently drafted to account for interception of the active substance by foliage, which estimates an other route to soil.

6. Page 3-9, line 15: I hope the development of an EURO-GENEEC will not be a US activity alone. I will be happy to contribute to this project.

7. Page 3-11, line 4: something I missing at the end: the sentence is not complete.

8. Page 3-11, line 25: the problem with monitoring is always the chance in capturing the pollution wave. The concentration of an active substance is always the highest shortly after application. Seldomly the sampling of the water is so close to the application time that this maximum concentration is hit.

9. Page 3-16, bottom end: again referring to monitoring, the design of monitoring programs is very important in judging the usefulness for validation of pesticide exposure modelling. It is not clear to me whether or not the current monitoring programs in the US are suitably for this purpose.

10. Page 3-20, line 10 – 15: I am very much in support of this remark and when possible I would like to contribute to this co-ordination.

11. Page 3-21, line 1 – 8: The process of Good Modelling Practice always includes several activities, as there are: 1) parameter estimation, the process of determining the descriptive processes with the 'correct' parameter values, i.e. depth of water body as a function of distance or the dispersive length in the description of dispersion in PRZM / PESTLA; 2) sensitivity analysis, the process of determining whether or not the model has the correct structure do the different processes add to the model in more or less equal importance, should processes be added or deleted; 3) validation, the process to determine whether or not the model performs equally well in other situations than the one used to calibrate the model.

12. Page 3-22, line 5 – 9: it seems that the position of field studies require quite some harmonisation in coming years. In the US, generally field studies are considered to have great interpretation problems, while in the EU field studies are considered the panacea to solve every doubt in the registration of PPPs.

13. Page 3-22, line 35 – 36 and page 3-23, line 1 –2: Although there are several models recommended in the EU to describe the input processes for the final fate models and also some screening models are supported, like SLOOT.BOX (Netherlands) and ABIWAS (Germany) example calculations will be performed with a selection of the recommended models: there will be drainage scenarios and run-off scenarios. For run-off the model PRZM will be used to determine the input and for drainage the Swedish model MACRO will be used. Drift is estimated with the newly developed German drift tables and the fate model will be the Dutch TOXSWA model. This id just to update you with the latest developments.

14. Page 3-29, line 23: I assume that degradates may be calculated separately with GENEEC considering it as an a.i. with the appropriate dose calculated with the fraction formed, the molar fraction and the dose of a.i. applied.

15. Page 3-30, table 3-2: concerning half lifes, I assume that 'if stable' means that the rate coefficient be set at zero and not the half-life: k = 0 9 (d^{-1}).

16. Page 3-40, line 32: I think some of the limitations are overdone. What would be an appropriate time series to consider when 36 years is considered a limitation?

17. Page 3-45, line 1: why is the San Diego supercomputer considered so important? The results of the calculations may be used in metaformat anyway, isn't it? But may be I do understand the relevance.

18. Page 3-45, line 12: the normal dependencies may be taken into account or is that not possible using MUSCRAT, like temperature and %om?

19. Page 3-67, table 3-6 continued: I propose to take into account here the normal seasonal variation as a first starting point. Additional extreme events may be considered as exceptional cases.

20. Page 3-69, table 3-7: it should be indicated why the proposed changes are considered necessary.

21. Page 3-69, table 3-7, point 63-5 and 63-6: I would be interested in knowing the temperature dependence of volatility and the usage in risk assessments. Does it concern a well-established QSAR? I am not convinced of the necessity. And why are question marks used here for melting point and boiling point?

22. Page 3-70, table 3-7, point 63-8 and 63-9: both values should be used to estimate Henry's law constant as an indication of volatility.

23. Page 3-70, table 3-7, point 63-10: the pKa may be used to determine whether or not the sorption is pH dependent. If the pKa is low (<4) sorption studies should be carried out with soils with a pH $\geq$ 6.

24. Page 3-70, table 3-7, point 63-11: Kow may be used to estimate sorption using a QSAR relation.

25. Page 3-70, table 3-7, point 161-2 to 4: the potential value of these items should be clearly indicated. How are these items used in the risk assessment process?

26. Page 3-70, table 3-7, point 163-1: is the change indicated here related to the current proposal in changing OECD106?

27. Page 3-70, table 3-7, point 163-1: in the Netherlands we use the aged leaching study to get a feeling for the importance of the leachability of minor metabolites. If the aged leaching study is carried out properly (e.g. an aging time of about one half-life) and the column has been measured after being sliced, the amount of RA in the leachate may indicate the relative importance of minor metabolite in the leachate.

28. Page 3-71, table 3-7, Lab Foliar Volatilisation: compare with 162-3, difference and use is not clear. And what is 'foliar applied run-off'?

29. Page 3-71, table 3-7, UV-Visible Adsorption Spectrum: What is the use in risk assessment?

30. Page 3-73, line 1 – 2: In the Netherlands registrants may e.g. sent in reports on specific DT50-values for sands in bulb application when they apply only this use.

31. Page 3-73, line 8: is it possible to give an example of the type of dissipation the authors are referring to here?

32. Page 3-77, top of page: it seems that something is missing here; only the last part of a sentence is given.

33. Page 3-87, line 29: again also here reference could be made to the OECD and EU activities on this subject as has been mentioned before.

34. Page 3-112, table 3-15: again, probably the rate coefficient has to be set to zero.

35. Page 3-113 and 3-114, table 3-16: again, probably the rate coefficient has to be set to zero.

36. Page 3-117, line 30: OK, here tile drainage is mentioned. Will it result in an additional scenario?

Chapter 4

1. Page 4-13, line 7 – 14: the objectives do not quite match with the ones mentioned on pages 2-6 and 2-17.

2. Page 4-14, line 8: is the incipient L(E)C50 considered a useful value in the US?

3. Page 4-19, line 4: referring to my earlier remark on this point it seems quite unsatisfactory and even not very scientific not to consider specific results of the studies deliberately. If a more thorough consideration of all data would result in shifting parts of the tiering approach of the risk assessment process to lower Tiers it seems OK to me. Looking at the figure outlining the risk assessment process it is possible to address toxicity items in the adequate risk assessment or to address the exposure. It is not established yet, and may it should not, what would be the most appropriate comparison to make with respect to the ratio of exposure and toxicity not taking into account he fact whether or not a probabilistic approach is used. So, the simple question is why not using the data when available?

4. Page 4-21, line 11: the same question as before may be raised. An advanced population analysis can be performed at the moment the data are available. If a company wants to raise data on this item they are free to do so, in my view. The cost – benefit analysis is up to them.

5. Page 4-27, line 27: it is not clear to me why there exists a trigger between the acute toxicity test and the chronic test. It is not usual in other aquatic toxicity testing, so, why to introduce it for sediment toxicity. From the ecotoxicological experience point of view is does not make sense. A correlation between these two items could not be found. In the EU this relation is not considered anymore (see also Van Leeuwen & Hermens).

6. Page 4-28, line 20: concerning microcosms / mesocosms there seems to develop another discrepancy between the EU and the US. In the US this type of studies is not considered in Tier 2 or 3, while in the US every governmental agency is asking for microcosm or mesocosm studies if the trigger values for a Tier 1 risk assessment are exceeded. In the CLASSIC workshop it was clearly indicated that the interpretation of the results of microcosm / mesocosm studies was extremely difficult. I assume that a lot of experience will be required at this point not only in performing the study but also in interpreting the results. Many decisions however will have to be taken shortly using these results. An additional problem for EPA and ECOFRAM to take into account is the question what to do if, based on EU decisions to carry out a microcosm / mesocosm study, the company delivers such a study to EPA even when the substance under consideration does not (yet) reach the right Tier to consider it.

7. Page 4-62, bottom end: in paragraph 4.4 several potential useful instruments have been indicated to apply in the risk assessment process if appropriate. It is

not quite clear, at least to me, which registration specific data are available or may be raised to use in this type of models. For TTE models it seems no problem because it may concern a different look and way of reporting the data. I would be ready to support the introduction of these methods in risk assessment but I am uncertain about other methods.

8. Page 4-65, line 17: in the Netherlands just recently some developments have taken place concerning small samples. I refer here to the sheets in my presentation.

9. Page 4-90, line 2: probably reference should be made to another section, because this is section 4.6.5.

10. Page 4-90, line 17 – 26: these lines should be deleted because of duplication in the earlier text under 4.6.5.

11. Page 4-105, bottom end: the effects part of the report so far gives a very good overview of all kind of scientific developments without further elaboration of proposals. In the recommendations several developments are supported for closer review. It seems that not only models to be considered to use or to recommend is important but also further guidance on how to use or develop a methodology for risk assessment is urgently needed. It is a pity that ECOFRAM did not further elaborate on this.

12. Page 4-107, line 13 – 19: in Tier 3 assessments sediment spiked toxicity tests are considered. Wouldn't it be more appropriate to consider especially or in addition also water spiked tests?

13. Page 4-117, line 16: several developments have taken place in recent years to guide registrant and registrators through the web of studies and complex interactions possible in the aquatic and also terrestrial environment. I have the impression but may be it is totally wrong that the outcomes of these activities gain more support in Europe than in the US. I am wondering what would be the reaction of the meeting on this statement.

14. Page 4-119, line 12: a conclusion supported by all participants to the CLASSIC workshop was that mesocosms were not suitable when fish was added or when fish were the organisms of concern. A specific study design would be required to answer potential risk assessment questions concerning fish.